4. 510(k) Summary

A. Submitter / 510(k) Sponsor

John W. Smith, Manager of Regulatory Affairs
Edwards Lifesciences
Research Medical
6864 South 300 West
Midvale, Utah 84047
USA

Phone (801) 565-6213

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B. Date Prepared

2000-05-18

C. Device Name

Steerable Retrograde Cardioplegia Cannula with and without Duraflo Treatment, SRC014MIB and DIISRC014MIB

Classified by FDA under 21 CFR § 870.4210, Cardiopulmonary bypass vascular catheter, cannula, or tubing.

D. Predicate Devices

Predicate Device A:	Retroplegia Cannula, RC014
Manufacturer:	Edwards Lifesciences Research Medical (RMI)
510(k) Number:	K880103

Predicate Device B:	Retroplegia Cannula, RC014MIB
Manufacturer:	Edwards Lifesciences Research Medical (RMI)
510(k) Number:	K880103

Predicate Device C:	Retrograde Cardioplegia Cannula with Duraflo Treatment, DIIRC014
Manufacturer:	Edwards Lifesciences Research Medical (RMI)
510(k) Number:	K991170

Predicate Device D:	Electrophysiology Catheter: Deflectable Tip
Manufacturer:	Cordis Webster
510(k) Number:	K955817

E. Device Description

The RMI Steerable Retrograde Cardioplegia Cannula is a multi-lumen cannula that has the following features:

A. A manually inflated/deflated occlusion balloon with a check valve and pilot balloon at the inflation port.

B. A separate pressure monitoring lumen extends from the soft, open tip to a 3-way stopcock at the proximal end.

C. A steerable tip which is manually controlled by a handpiece attached to the proximal portion of the device.

D. A malleable insertion stylet.

Product codes beginning with a "DII" denote devices that are treated with Edwards Lifesciences' proprietary heparin coating, Duraflo. The Steerable Retrograde Cardioplegia Cannula is offered in a version with Duraflo treatment.

Each Steerable Retrograde Cardioplegia Cannula is individually packaged sterile and non-pyrogenic in a sealed, peel-type pouch.

F. Intended Use

The RMI Steerable Retrograde Cardioplegia Cannula is intended for intra-operative delivery of blood or cardioplegia solution.

Extracorporeal circuit components with the Duraflo treatment are indicated for use in cardiopulmonary surgery when a heparin-treated blood path is desired.

G. Summary of Comparison, Proposed and Predicate Devices

The proposed device is substantially equivalent to the cited predicate devices in intended use, technology, materials, and design.

The proposed device consists of a modification to the marketed device cited as Predicate Device A. The modifications consist of:

- Predicate device A, modified to use a manually inflated balloon which is identical to that used on Predicate B, instead of the self-inflating balloon included in the original Predicate A.
- Addition of the Duraflo heparin treatment, identical to that used in Predicate C, on appropriate models of the proposed device.
- Addition of a steering mechanism, similar to that cleared as Predicate Device D, which allows for deflection (or "steering") of the cannula tip.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2000

Mr. John W. Smith
Manager, Regulatory Affairs
Edwards Lifesciences LLC
Research Medical
6864 South 300 West
Midvale, Utah 84047

Re: K001565
Trade Name: Steerable Retrograde Cardioplegia Cannula with and without Duraflo Treatment
Regulatory Class: II
Product Code: DWF
Dated: May 18, 2000
Received: May 19, 2000

Dear Mr. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), or for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

D. Indications for Use Statement

510(k) Number (if known): K001565

Device Name: Steerable Retrograde Cardioplegia Cannula with and without Duraflo Treatment

Indications for use:

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Extracorporeal circuit components with the Duraflo treatment are indicated for use in cardiopulmonary surgery when a heparin-treated blood path is desired.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001565

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)